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| 10/566,226      | 01/27/2006  | Gilad Lavi           | S2082/20003         | 3732             |

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| EXAMINER |
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SHELL, LAURA C

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| ART UNIT | PAPER NUMBER |
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3767

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09/05/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/566,226 | <b>Applicant(s)</b><br>LAVI ET AL. |  |
|                              | <b>Examiner</b><br>LAURA C. SCHELL   | <b>Art Unit</b><br>3767            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by McWethy et al. (US 2003/0229314). McWethy discloses an injection device (Figs. 1-6) comprising: a housing (Fig. 2, 50) having a proximate end (near 52) and a distal end (near 51), the distal end having an opening therein (near 51); a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (within 13) fixed to the distal end of the cartridge barrel (Figs. 1 and 4); a stopper (Fig. 4, 38) within the cartridge barrel; a driver (42) coupled to the stopper; a shield (20) coupled to the housing and slidable between a retracted position (Figs. 1, 4 and 5) and an extended position (Fig. 6); shield driver means (24) activatable to urge

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the shield from the retracted position to the extended position; and sensor means (46) forming a portion of said driver (46 is connected and forms a portion of driver 42) and in slidable contact with an interior surface of the housing (Fig. 5 discloses that 46 slides along the interior of the housing and contacts 26 to release the shield), the sensor means arranged to detect an end profile of the housing and to automatically trigger activation of the shield driver means upon detection (Fig. 5 discloses that 46/sensor means detects an end profile of the housing (46 detects 54 which is being interpreted as the end profile of the housing. Please note that Applicant has not specified which end of the housing it much sense/contact) and this triggers the release of 26 which automatically triggers the activation of the shield driver means upon detection).

In reference to claim 2, McWethy discloses that the shield driver means comprises a coil spring (24) within which the cartridge barrel is located.

In reference to claim 3, McWethy discloses a release mechanism (26).

In reference to claim 4, McWethy discloses that the driver is arranged to be manually pushed through the housing, the driver carrying the shield driver means to a shield activation point (Fig. 5).

In reference to claim 5, McWethy discloses that the coil spring is fixed at its proximal end to the driver and the spring release mechanism fixes the spring to the driver at its distal end (Fig. 2).

In reference to claim 6, McWethy discloses that the shield driver means additionally provides a driving force for said driver (Fig. 5).

In reference to claim 7, McWethy discloses that the coil spring is fixed at its proximal end to the housing, and the spring release mechanism fixes the spring to the driver at its distal end (Fig. 5).

In reference to claim 8, McWethy discloses that the sensor means comprises one or more deformable arms attached or formed integrally with the driver (Fig. 5).

In reference to claim 9, McWethy discloses that each arm is biased against the exterior surface of the cartridge barrel and arranged to follow the surface profile of the barrel (Figs. 5 and 6).

In reference to claim 10, McWethy discloses that the release mechanism comprises a catch provided on a radial outer surface of each deformable arm (Figs. 5 and 6).

In reference to claim 11, McWethy discloses that said driver and said sensor means are a singled molded plastic element (Fig. 5).

Claims 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by McWethy et al. (US 2003/0229314). McWethy discloses an injection device (Figs. 1-6) comprising: a cartridge barrel (30), said barrel arranged to contain a stopper (Fig. 4, 38) and fluid therein and wherein said barrel has a second open end and a second end having a radial flange adjacent to the second end (Fig. 4, flange 54); a needle cannula (12) having a sharp distal end and a second open end, the fluid being in communication with said needle second end; a housing (50) surrounding said barrel, said housing

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having a distal open end adjacent the needle and a proximate end having a flange receiving the radial flange of the barrel; a shield (20) releasably retained by the housing, said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Fig. 4); a driver (42), said driver positioned partially within said housing, said driver equipped with at least one deformable side arm (46) sensing the end of the barrel (Fig. 5 discloses that 46 detects 54 which is at the end of the barrel. Please note that Applicant has not claimed which end of the barrel must be sensed.), said driver slidingly located within said housing for moving the stopper forward (Fig. 5); and a biasing spring (24), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (Fig. 5 discloses that when 46 contacts/senses 54 (the end of the barrel) this releases 26 which automatically releases the shield to cover the needle).

In reference to claim 13, McWethy discloses that the biasing spring is carried by the driver and is released to bias the shield when the end of said barrel is reached (Fig. 2).

In reference to claim 14, McWethy discloses that the driver has two sensor elements to detect the end of the barrel (Fig. 2 and 5).

In reference to claim 15, McWethy discloses that the housing and shield are equipped with latches (Fig. 2).

In reference to claim 16, McWethy discloses that said latches prevent premature release of the shield (Figs. 4 and 5).

In reference to claim 17, McWethy discloses that said latches retain the shield in a needle shielded position (Figs. 4 and 5).

In reference to claim 18, McWethy discloses that the driver is deformable during assembly (Figs. 2 and 5).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-70 of copending Application No. 10/566333. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications claim similar if not identical subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/899923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications claim similar if not identical subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 11/666851. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications claim similar if not identical subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767